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Submission to the

Joint Standing Committee on Treaties

on

The Australia-United States Free Trade Agreement (AUSFTA)

April 2004

INTRODUCTION

The Doctors Reform Society (DRS) is an organisation of doctors formed in 1973 to support the introduction in Australia of universal health insurance, initially Medibank, now Medicare. The DRS continues to advocate for equitable universal access to quality health care for all members of Australian society. The DRS welcomes this opportunity to contribute our views to this inquiry.

The DRS has previously addressed health implications of economic globalisation, the General Agreement on Trade in Services (GATS) of the World Trade Organisation (WTO) and the bilateral free trade agreement (FTA) between Australia and the United States (US) in submissions (2001-2003) to the Department of Foreign Affairs and Trade (DFAT) and to the Senate Inquiry on the General Agreement on Trade in Services and the proposed Australia-US Free Trade Agreement.

The fundamental purpose of international trade agreements is to reduce barriers to trade. Barriers to trade in services are largely domestic regulations. The DRS strongly believes health related services should not be negotiated in trade agreements. The DRS believes the market ideology of trade agreements is a threat to universal health insurance schemes like Medicare, the Pharmaceutical Benefits scheme and public health principles. In this submission the DRS will address our concerns specifically in relation to health care issues and the Australia-United States Free Trade Agreement (AUSFTA).

The Doctors Reform Society is concerned that public health policy has been embodied within the AUSFTA. Australian health care policy, including that for pharmaceuticals, will be linked by the AUSFTA to the nation with arguably the most inefficient and inequitable health and pharmaceutical system of developed nations. Public health principles, equity and universality will not be priorities.

THE AUSTRALIA – UNITED STATES FREE TRADE AGREEMENT

The DRS believes benefits for Australia from the AUSFTA are doubtful and the potential cost to the community great. The predicted economic gains from an AUSFTA determined in the original study by the Centre for International Economics commissioned by the government were extremely modest, only 0.3 percent of GDP per year after 10 years and this was if all trade barriers were removed [1]. Other economic studies by ACIL consultants and the Productivity Commission predicted losses[2, 3]. The gains in agriculture have been much less than predicted.

Summary

The main concerns of the DRS in relation to health care are:

- Public services are not protected from the market thrust of the agreement;
- Health care is not unambiguously excluded is thus open to market forces and US style corporatisation;
- Health professional qualifications, licensing and standards within health facilities are not to be 'unnecessary barriers to trade' and are to be 'not more burdensome than necessary';
- The US government and pharmaceutical companies will have greater influence over the functioning of the PBS compromising public health principles and the price control capacity of the Pharmaceutical Benefits Advisory Committee (PBAC);

- The introduction of an 'independent review process' of negative PBAC decisions will lead to greater pressure on the PBAC to approve more expensive drugs even when they may not give any significant advantage over drugs that are already available;
- The creation of a 'Medicines Working Group' (MWG) with the US government will be another mechanism for the US pharmaceutical industry through their government to continue to pressure the Australian government to make further changes to pharmaceutical policy that would lead to greater profits for the US industry;
- Increased patent rights for pharmaceutical companies will delay the entry of new generic drugs onto the market by the generic industry maintaining higher prices for longer and thus higher costs for the PBS and ultimately the Australian people;
- The beginning of direct-to-consumer advertising (DTCA) of pharmaceutical drugs by inclusion of a clause on internet DTCA. This opens up DTCA for further 'discussion' and negotiation under trade priorities rather than public health merits. There will be opportunity for further pressure from pharmaceutical companies.
- What is considered necessary to protect human life or health; whether a particular health service is a social service for a public purpose; public health measures such as tobacco and alcohol control; and pharmaceutical policy - all are open to interpretation by trade dispute panels whose priority is reducing trade barriers not public health;

Sections in the text of the Australia-US Free Trade Agreement (AUSFTA) that are relevant to health care include:

- Chapter 10 Cross-Border Trade in Services;
- Chapter 13 Financial services (includes health insurance);
- Annex II (includes exclusions for Social services);
- side letter regarding gambling, alcohol, firearms and tobacco;
- Chapter 2: Market Access, Annex 2.C Pharmaceuticals;
- Chapter 17 Intellectual Property Rights;
- side letter on the Pharmaceutical Benefits Scheme (PBS).

The Details

- *Exclusions:*

Chapter 10 deals with trade in services. As the AUSFTA is a 'top down' agreement using a negative list approach, any service not explicitly excluded automatically comes under the terms of the agreement. This is in contrast to a 'bottom-up' agreement with a positive list of what is included. The issue of clearly defining exclusions is thus crucial.

Chapter 10 Cross-Border Trade in Services, Article 10.1 Scope and Definition, replicates the contentious language used in the World Trade Organisation (WTO) *General Agreement on Trade in Services (GATS) Article 1.3* for exclusion of *'services supplied in the exercise of governmental authority'*:

> ARTICLE 10.1 : SCOPE AND COVERAGE
> 4. This Chapter does not apply to:
> (e) services supplied in the exercise of governmental authority within the territory of each respective Party.
> A **service supplied in the exercise of governmental authority** means any service which is supplied neither on a *commercial basis*, nor in *competition with* one or more service suppliers. (italics added)

This gives little assurance for public services including health care. The recent report of the Senate Inquiry into the General Agreement on Trade in Services and the Proposed

Australia-United States Free Trade Agreement highlighted concerns with interpretation of this article [4]. The WTO has previously stated:

> 39. The hospital sector in many countries, however, is made up of government- and privately-owned entities which both operate on a commercial basis, charging the patient or his insurance for the treatment provided. Supplementary subsidies may be granted for social, regional and similar policy purposes. *It seems unrealistic in such cases to argue for continued application of Article 1:3 and/or maintain that no competitive relationship exists between the two groups of suppliers or services. In scheduled sectors, this suggests that subsidies and any similar economic benefits conferred on one group would be subject to the national treatment obligation under Article XVII.* [italics added] [5]

General exceptions for services (*Chapter 22 General Provisions and Exceptions, Article 22.1 General Exceptions subparagraph 2.*) are the same as *GATS Article XIV* which includes measures that are:

> a) *necessary* to protect public morals or to maintain public order;
> b) *necessary* to protect human, animal or plant life or health;
> c) *necessary* to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement including those relating to:
> i) the prevention of deceptive and fraudulent practices or to deal with the effects of a default on services contracts;
> ii) the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts;
> iii) safety;
> (italics added)

With the important proviso:

> ... that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail; or a disguised restriction on trade in services

In the side letter regarding gambling, alcohol, firearms and tobacco, it is stated that regulation of retail trade services for tobacco products, alcoholic beverages, or firearms will typically fall within the exceptions provided under subparagraphs (a), (b), and (c) (iii) of *GATS Article XIV*. The WTO has previously used a very narrow interpretation of what is deemed 'necessary' and interpreted that the measure must be the least trade restrictive possible to achieve its objective. This standard gives priority to free trade and restricts national measures to protect public health.

Annex II contains exclusions for social services including health care and states:

> Australia reserves the right to adopt or maintain any measure with respect to the provision of law enforcement and correctional services, and the following services *to the extent that they are social services established or maintained for a public purpose*: income security or insurance, social security or insurance, social welfare, public education, public training, health and child care. (italics added)

A crucial question is how will health care be defined. As the agreement uses a negative list approach, it is essential for clarity.

Although health care is not specifically stated as 'public', whether public or private it would have to be deemed a *'social service established or maintained for a public purpose'* to be excluded. A US definition of this can differ markedly from other interpretations. Market ideology which dominates the US health system interprets many areas of health care not

as social services for a public purpose. Rather, individual responsibility and the relationship between the provider and consumer (patient) are paramount.

There have been differences between Canadian and US interpretations in relation to health care exclusions in the similarly worded NAFTA. The US Trade Representative has indicated a narrow interpretation that the Annex II exclusion only applies where services are both entirely government financed and publicly delivered [6, 7]. The more the system is privatised, the less likely is the claim that all services are provided for a public purpose. The complex web of public-private relationships in Australia's health sector could expose many areas of health care to AUSFTA trade obligations. Self-definition has not applied in trade dispute procedures.

The classification system for services that will be used is not stated. WTO classification places medical, dental, nursing, midwifery, physiotherapy and paramedical services not occurring in a hospital under professional services in *Business Services* and *not* in *Health Related and Social Services* as in the *UN Central Product Classification*. Health insurance is classified under non-life insurance in *Financial Services* which includes insurance, banking and other financial services. There is no mention of an exclusion of health insurance in *Chapter 13 Financial services* or *Annexes III* and *IV* (which lists exempt non-conforming measures in relation to Chapter 13). It appears that this places the health insurance sector under the full obligations of the agreement.

The Australian negotiators have not clarified these issues.

Articles 10.2 National Treatment, *10.3 Most-Favoured-Nation*, *10.4 Market Access*, and *10.5 Local Presence* apply to services that are not excluded. Similarly, *Articles 13.2 National Treatment*, *13.3 Most-Favoured-Nation*, *13.4 Market Access for Financial Institutions* and *13.5 Cross-Border Trade* apply to financial services not excluded.

This all seems to lead to murky definitions open to interpretation by trade officials whose priority is reducing trade barriers not public health.

- *Professional Qualifications and Standards:*

Article 10.7: Domestic regulation 2. (a), (b) and (c) that apply to qualifications and standards in the health field is the same as *GATS Article VI Domestic Regulation 4. (a), (b) and (c)*:

> 4. With a view to ensuring that measures relating to qualification requirements and procedures, technical standards, and licensing requirements do not constitute unnecessary barriers to trade in services, each Party shall endeavour to ensure, as appropriate for individual sectors, that such measures are:
> a) based on objective and transparent criteria, such as competence and the ability to supply the service;
> b) *not more burdensome than necessary* to ensure the quality of the service; and
> c) in the case of licensing procedures, not in themselves a restriction on the supply of the service.
> (italics added)

This covers professional qualifications and licensing, and licensing and accreditation of facilities, financing and funding of services and overall administration. Of concern, this applies to non-discriminatory measures.

- *The Pharmaceutical Benefits Scheme:*

The Pharmaceutical Benefits Scheme (PBS) is dealt with specifically in *Chapter 2: Market Access, Annex 2.C Pharmaceuticals* and the *side letter on the PBS*. The Agreed Principles

of *Annex 2.C* uses the language of the pharmaceutical industry and concentrates on the importance of *'innovation' and 'research and development'* and ominously *'the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical'*. There is no mention of equity or universal access to affordable medicines. This is in complete contrast to the objectives of the PBS - comprehensiveness, universality and responsible community cost.

The pharmaceutical industry has consistently used rewarding innovation and research and development (R&D) to defend high US prices. This is despite the pharmaceutical industry having been the most profitable industry in the US for each of the past 10 years, the most generous campaign contributor in the world, spending twice as much on marketing as on R&D and the fact that most new drugs on the market are replacements for cheaper generic versions [8-15].

Both *Annex 2.C* and the *side letter on the PBS* incorporate Pharmaceutical industry input into the Pharmaceutical Benefits Advisory Committee (PBAC) approval process both before and after a decision has been made. The side letter states that before approval companies are provided with:

> 1. (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;
> (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);
> (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and
> (d) sufficient information on the reasons for its determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

If not happy with a negative decision, pharmaceutical companies are given a further review process:

> 2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list. (side letter on the PBS)
>
> 2. (f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination. (Chapter 2: Market Access, Annex 2.C Pharmaceuticals)

The structure of the 'independent' review has not yet been determined. The Australian negotiators insist the independent review is not an appeals process and will not be able to overturn PBAC decisions. This is a play on semantics. Although not having direct power, decisions will be influenced, otherwise why have the process? There will be greater pressure to approve more expensive drugs that may not give any significant advantage over drugs that are already available. A further appeals process had previously been rejected in the Tambling Review of the PBS [16].

In *Chapter 2: Market Access, Annex 2.C Pharmaceuticals* there is a proviso to establish a Medicines Working Group (MWG) to promote discussion *'including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes'*. It is to *'comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials'*.

It will provide for continued dialogue between the United States and Australia on emerging health care policy issues. Again the emphasis is on the pharmaceutical industry with no

mention of universal access to affordable medicines. This is unbalanced and based on commercial principles. This 'discussion group' is with a country where 40 per cent of its citizens cannot afford access to necessary drugs and many go to Canada and Mexico to buy them.

The Bush administration's strategy in relation to pharmaceutical policy has been to undermine drug price controls in other developed countries. President Bush's recently passed Medicare bill includes provisions to scrutinise *'protectionist'* programs in foreign countries and if necessary eliminate them through free trade negotiations. The bill specifically forbids the government to use its influence to negotiate lower drug prices in its own country [17]. That provision was a key goal in the lobbying of the pharmaceutical industry.

There is the conviction that *'pricing constraints'* in other countries shift *'the burden for R&D'* to the consumers in the US. US Republican Senator Kyl, who was part of the US negotiating team, told a US Senate finance committee after the AUSFTA was released that a way to address this *"is to get the other countries of the world to help bear part of the burden of the R&D"* [18].

Senator Kyl said that the final agreement was a *"breakthrough"* in respect to pharmaceuticals but only the beginning of negotiations *"... I know that there is much more work that needs to be done in further discussions with the Australians."* Senator Graham stated at the hearing that the agreement *"has had the effect of injecting more marketplace in the Australian pharmaceutical distribution system"* [18].

There have been concerns raised in the United States. House of Representatives Democrat Leader Nancy Pelosi and eight other Democrats wrote to President Bush earlier this year after reading the text of the agreement saying:

> *(g)iven that far too many Americans cannot afford access to life-saving or life-prolonging medicines, it is astounding that the United States may seek to impose those shortcomings not only on Australia today but on the rest of the world tomorrow.* [19]

A letter to the US Trade Representative (USTR), Mr Robert Zoellick, written by Democrat Congresswoman Rosa DeLauro and signed by seventeen other members of Congress said:

> *(w)e are deeply opposed to the trade office being used by the US pharmaceutical industry to achieve its strategic objective of raising worldwide drug prices to the level now paid by US consumers.* [20]

Once listed, further opportunity for drug prices to keep rising is assured due to the statement in the *side letter on the PBS*:

> 4. Australia shall provide opportunities to apply for an adjustment to a reimbursement amount.

Although the Australian negotiators say this provision already exists and will not change things, it is now embodied in the trade agreement and thus under the obligations and possible dispute procedures of the AUSFTA.

All this amounts to the US government and pharmaceutical companies having an influence in the workings of the PBS. Australian government representatives and negotiators are keen to emphasise that much of the agreement in relation to pharmaceutical policy already

occurs and reflects the 'status quo'. Discussions and opportunities for comment already occur during the approval process and a company can re-submit its case if rejected.

A big distinction, however, is that this has occurred under Australian guidelines with public health principles and the welfare of the Australian people at heart. Now it will be incorporated in a trade agreement with another nation where the aim is to reduce trade barriers. Pharmaceutical policy will be institutionalised in a trade agreement.

- *Pharmaceutical Patents:*

Chapter 17 Intellectual Property Rights Articles 9 Patents and *10 Measures Related to Certain Regulated Products* are relevant to patents on pharmaceuticals. Analysis by The Australia Institute concludes that the changes to Australia's pharmaceutical patent laws in the agreement will result in delays to the arrival of generic medicines resulting in higher cost for the PBS. This includes extensions of patent periods in some circumstances and changes that make it easier for drug companies to raise legal objections and delay the production of generic drugs. In the US, drug companies have used such legal tactics aggressively. Since the PBS price control system relies on comparisons with cheaper generic drugs, delays in the production of generic drugs will contribute to price rises. All of this will inevitably cost the taxpayer and the consumer.

Professor Peter Drahos, an Australian expert on intellectual property law from the Australian National University has also said that the stringent US patent standards in the agreement which go far beyond the international norm will benefit US companies at the expense of Australian bio-tech and generic companies and the wider community [21].

The overall deal pushes towards higher prices and costs. Pharmaceutical companies will have their profits increased from the pockets of ordinary Australians.

- *Direct-to-consumer advertising:*

Direct-to-consumer advertising (DTCA), is mentioned in *Chapter 2: Market Access, Annex 2.C Pharmaceuticals 5. Dissemination of Information.* DTCA by pharmaceutical companies of approved pharmaceuticals will be allowed on the internet as long as it is *'truthful and not misleading' and 'includes a balance of risks and benefits'*. The negotiators state that this again reflects the 'status quo' as it states *'as is permitted under each Party's laws, regulations and procedures'* and there is no intention of changing the laws. There is no satisfactory answer as to why it is mentioned in the agreement and whether this could result in DTCA being 'discussed' in the MWG and further negotiations where further pressure will come to bear. This could be the first step to more widespread DTCA.

- *Dispute Process:*

Any dispute arising from the agreement may ultimately be determined by a dispute settlement panel of three, the chair selected from a group who *'have expertise or experience in law, international trade, or the resolution of disputes arising under international trade agreements'*. Except for disputes involving enforcement of labour laws and environmental laws there is no requirement for panelists to have expertise or experience relevant to the subject matter under dispute. Hearings do not have to be public and the decision does not have to be made public and cannot be appealed. The panel can order that a law be changed or compensation paid. (*Chapter 21 Section B: Dispute Settlement Proceedings*). *Article 21.8: Rules of Procedure 1. (d)* and *3.* appears to provide a token gesture to other perspectives. The article states the panel may invite advice or accept written views of non government representatives as long as both sides agree:

1. (d) that the panel shall consider requests from non governmental persons or entities in the Parties' territories to provide written views regarding the dispute that may assist the panel in evaluating the submissions and arguments of the Parties and provide the Parties an opportunity to respond to such submissions and arguments;

3. On request of a Party, or on its own initiative, the panel may seek information and technical advice from any person or body that it deems appropriate, provided that the Parties so agree and subject to such terms and conditions as the Parties may agree.

What is considered necessary to protect human life or health, whether a particular health service is a social service for a public purpose, whether health qualifications or regulations are more burdensome than necessary, whether tobacco control regulations are the least trade restrictive or whether Australia is keeping to the obligations under *Annex 2.C*

Conclusion

Public health is a notable area of concern with the Australia-US FTA. The DRS believes any potential benefits for Australia from the AUSFTA are outweighed by potential costs to the community.

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